Kentucky
Hospital
Association
Representing Kentucky Health Care Organizations

December 5, 2014

Diona Mullins
Policy Advisor
Office of Health Policy
275 E. Main St., 4W-E
Frankfort, Kentucky 40621

Re: Comments on the Kentucky Certificate of Need Program

Dear Ms. Mullins:

Kentucky Hospital Association (KHA) is writing to submit comments on the Certificate of Need (CON) program, as requested in the Cabinet's special memorandum dated October 8, 2014. KHA is a member driven association representing all 130 Kentucky hospitals. We appreciate the opportunity to submit the attached white paper, "Certificate of Need: Stabilizing Force for Health Care Transformation," as our comments.

KHA's Certificate of Need Committee and Board of Trustees recognized the need earlier this year to perform a comprehensive study of the value of Kentucky's CON program as it relates to the statutory intent. KHA engaged a consultant, Dan Sullivan, to assist in our research of the history of CON, its value and the experience of other states that have repealed or significantly changed their CON program. KHA is glad for the Cabinet's efforts to study the policy more closely, especially as it relates to the significant changes that are occurring within the health care delivery systems.

KHA's report will demonstrate that Kentucky's CON program is an essential stabilizing force in place to create the needed environment for existing providers and health systems to engage in emerging payment models and demonstration projects geared toward population health and improving the continuum of care, which are the fundamental goals in Health Care Reform and achieving The Triple Aim.

Again, we are grateful for the opportunity to share with the Cabinet our comments regarding the CON program and we welcome the occasion to work collaboratively with the Cabinet to implement policy and data sharing and evaluation to promote health care transformation, improved population health and shared cost savings.

Sincerely,

Michael T. Rust

Michael T. Rust
President

Certificate of Need:
Stabilizing Force for Health Care Transformation

Response by the Kentucky Hospital Association to
Special Memorandum on "Certificate of Need Modernization:
Core Principles Request for Stakeholder Input"

December 8, 2014

Report prepared by:
Daniel J. Sullivan of Sullivan Consulting Group and
The Kentucky Hospital Association

Executive Summary

The Kentucky Hospital Association ("KHA") submitted a White Paper entitled "Certificate of Need: Stabilizing Force for Health Care Transformation" in response to the Special Memorandum issued by the Cabinet for Health and Family Services' Office of Health Policy {"the Cabinet") on October 8, 2014 entitled "Certificate of Need Modernization: Core Principles, Request for Stakeholder Input" (Memorandum).

The Cabinet stated: "In Kentucky, health reform has highlighted the need to modernize the Certificate of Need (CON) program to better enable health care providers to work toward improved health for all Kentuckians. Thus, in considering changes to the CON program and the State Health Plan in connection with the periodic update process, the Cabinet for Health and Family Services (CHFS) will adopt an holistic approach to revisions, with the vision of achieving the Triple Aim: better value, better care, and population health improvement."

Our White Paper accomplishes two goals: responding to the request for comments on how a modernized CON program can support health care transformation and demonstrating the historical and current value of the CON program in Kentucky while reflecting on consequences of eliminating CON as has occurred in some other states. A major basis for the Cabinet's determination that changes to the Kentucky CON are needed is a report prepared by the consulting firm Deloitte Consulting, LLP, entitled *Kentucky Healthcare Facility Capacity Report,* released December 2013.This report is analyzed in detail within our the white paper. The impact of eliminating CON regulations on rural hospitals and safety net hospitals, which provide essential access to health care Kentucky's most vulnerable citizens, was also addressed.

The Cabinet identified "core principles" that would guide its efforts to modify the existing CON regulations; however, our analysis demonstrates that significant modifications to or elimination of Kentucky's CON regulations would be inconsistent with achieving the Cabinet's objectives embodied in these principles.

- Principle 1: Supporting the Evolution of Care Delivery – The evolution in health care delivery that is at the heart of Health Care Reform is not frustrated by CON regulation. The driving force for new models of care is altering payment incentives, which are independent of CON regulations. However, CON is a stabilizing force which allows existing providers to embrace new payment models, like accountable care organizations and payment bundling, which require a level of risk to be taken by providers. CON deregulation under current payment conditions would result in greater fragmentation rather than enhancing the integration of care.

- Principle 2: Incentivizing Development of a Full Continuum of Care – The development of a full continuum of care is precisely the objective of new delivery models that are evolving. The creation of such delivery systems is not impacted by Kentucky's CON regulations. In most parts of Kentucky today, there is sufficient availability and capacity of health services to allow new models of care to be developed without allowing unchecked proliferation of new services and facilities. The focus of health care transformation centers on improving

population health. Primary care and prevention services for the most part are not covered by the CON program in Kentucky.

- Principle 3: Incentivizing Quality – Quality of care will be a function of the care management systems implemented by organizations. CON deregulation would likely have the effect of diminishing quality of care by reducing volumes across all providers and stretching scarce resources over a greater number of providers. CON standards currently support quality as CON criteria seek to ensure that new facilities operate at volumes that are sufficient to provide quality services as well as assuring that new volume does not come at the expense of existing providers where the lowering of their volumes could reduce quality of existing programs.

- Principle 4: Improving Access to Care – CON deregulation could have the effect of reducing access to care by destabilizing local health care systems. Smaller, rural hospitals and safety-net hospitals in particular are vulnerable to the loss of profitable patients to private organizations that would be developed without CON standards in place. Additionally, new providers likely to enter the market if CON is repealed or weakened would probably target serving patients with commercial insurance which would have an adverse impact on improving access for Medicaid or indigent patients. This has been demonstrated in other states like Ohio.

- Principle 5: Improving Value of Care - There is no evidence that states without CON programs offer higher value care. To the contrary, in most cases, states without CON have significantly greater duplication of resources and operate on average at lower volumes per provider.

- Principle 6: Promoting Adoption of Efficient Technology – There is simply no relationship between the adoption of efficient technology and CON regulation. Administrative and clinical information systems are not subject to specific CON regulations in Kentucky. With the exception of a few high dollar types of equipment, hospitals and other providers are able to acquire new equipment and technology without facing impediments from the CON program.

- Principle 7: Exempting Services for Which CON is No Longer Necessary – There are no services that the Deloitte Report recommended for elimination of CON review that would appropriately be deregulated. The concern with ensuring sufficient capacity in the future to accommodate a growing base of insured Kentuckians is not based on objective analysis. There are no capacity issues or other considerations that would require the elimination of CON to ensure adequate availability of care. The impact on rural hospitals and safety-net hospitals must also be considered when exempting services from review, and such changes could challenge the ability of these providers to offer the same level of access in the future. It is premature today to make changes that will result in greater fragmentation rather than integration of providers. The CON program should be continually reviewed, as it has been, and revised in accordance with health planning principles which consider actual changes in the delivery system and data documenting needs and gaps in services.

Conclusion

New health delivery systems will be driven by new payment models, which are already being implemented through Medicare payment reform, and which is the key driver, rather than the elimination of CON regulations. In fact, the reduction or elimination of CON regulations in Kentucky could discourage efforts of Kentucky providers to adopt new models of care delivery because markets will be more fragmented and financial resources will more be limited. The Kentucky CON program will provide stability and predictability during the difficult transition period to value-based care delivery and population health management where providers assume more financial risk.

Kentucky's CON program as currently constituted is not onerous and allows considerable flexibility to providers to undertake needed projects. There is ample capacity in Kentucky's existing health care system, according to published utilization reports, to accommodate much of the future growth that may or may not arise from an expanded pool of insured individuals. Lessons from other states that have deregulated should be a cautionary tale to Kentucky. The elimination of CON review will create significant short-term disruptions with no long-term payback.

KHA does oppose significant changes to CON regulations which would be contrary to the statutory goal of the program, to promote quality services and cost containment, and would result in substantial proliferation of unneeded health services. KHA does support changes to home health standards that recognize the unmet needs of new delivery models to provide a comprehensive continuum of care. KHA also supports a change that would allow hospitals seeking to convert through nonsubstantive review, to a different model of offering only emergency and outpatient services.

The evolution of health care delivery in Kentucky, whatever final form it takes, is dependent on a stable health care market through continuation of the CON program. Selected modifications to regulations responding to changing conditions have been and should continue to be part of Kentucky's CON program. CHFS should consider changes in CON regulations to accommodate the special needs of new delivery models and other components of a population health system in the future that are based on the needs of communities rather than adopt a free-market approach that will not ensure uniform access to care for all citizens of the Commonwealth. The most pressing need is for greater access to primary care and medical homes, and these services are not even generally regulated under CON.

Background and Purpose

This paper was prepared on behalf of the Kentucky Hospital Association to respond to the Special Memorandum issued by the Cabinet for Health and Family Services' (CHFS) Office of Health Policy on October 8, 2014 entitled "Certificate of Need Modernization: Core Principles, Request for Stakeholder Input" (Memorandum).[1]

The Memorandum states: "In Kentucky, health reform has highlighted the need to modernize the Certificate of Need (CON) program to better enable health care providers to work toward improved health for all Kentuckians. Thus, in considering changes to the CON program and the State Health Plan in connection with the periodic update process, the Cabinet for Health and Family Services (CHFS) will adopt an holistic approach to revisions, with the vision of achieving the Triple Aim: better value, better care, and population health improvement."

CHFS identified the following core principles that will guide its process to review the CON program:

- Supporting the Evolution of Care Delivery.
- Incentivizing Development of a Full Continuum of Care.
- Incentivizing Quality.
- Improving Access to Care.
- Improving Value of Care.
- Promoting Adoption of Efficient Technology.
- Exempting Services for which CON is no longer necessary.

CHFS has requested feedback from all interested stakeholders regarding possible strategies for and changes to the CON program that would further the implementation of the identified principles. "Policy papers are strongly encouraged, as are specific and data-supported responses to the Deloitte Healthcare Facility Capacity Report released in December 2013."

The Kentucky Hospital Association (KHA), established in 1929, represents hospitals, related health care organizations, and integrated health care systems dedicated to sustaining and improving the health status of the citizens of Kentucky. The Kentucky CON Program directly impacts many of the programs and services rendered by KHA members.

This paper will first consider the extent to which changes in the CON program will address the core principles that CHFS has identified and "enable health care providers to work toward improved health for all Kentuckians." In addition, it will evaluate the history and evolution of CON review in Kentucky and the nation, as well as research on the efficacy of CON regulation. It will also explore the impact of CON deregulation on states proximate to Kentucky. Specific comments will be offered on the Deloitte Report and its conclusions, which CHFS has requested. Finally, the paper will offer conclusions and recommendations regarding the need for significant changes to Kentucky's CON program.

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[1] This paper was prepared by Daniel J. Sullivan of Sullivan Consulting Group, a national health care planning firm. Mr. Sullivan has been involved in the preparation of CON applications and development of CON regulations and policies for more than 30 years including extensive work with the Kentucky CON program during that time.

CON Deregulation and the Cabinet's Core Principles

KHA welcomes the opportunity to work collaboratively with the CHFS to ensure that Kentucky embraces health care transformation. The CON program is crucial in creating a stable market to foster health care transformation which is largely dependent on payment reform. KHA shares CHFS' concern regarding potential barriers to the development of a more effective health care delivery system. However, KHA believes that CHFS' focus on significantly changing or eliminating key components of the Kentucky CON program in order to achieve that objective is premature or misplaced. Payment models, not CON regulations, drive health care delivery transformation. The centerpiece of the Patient Protection and Affordable Care Act of 2010 (PPACA) is the development of new payment models that encourage the formation of new health care delivery structures such as Accountable Care Organizations (ACOs) that will integrate a range of providers seeking to meet the Triple Aim objectives of better value, better care, and population health improvement.

Medicare plays a critical role in shaping the delivery of services given that it is the largest single payer of services. Virtually all of the major changes in the delivery of health services in this country over the past four decades have resulted from changes to Medicare reimbursement policies. For example, the implementation of the Medicare Inpatient Prospective Payment System that shifted reimbursement from a cost basis to a prospective rate per case dramatically decreased inpatient hospital utilization over the course of two years. Changes in Medicare's policies regarding ambulatory surgery centers, home health care, skilled nursing care, and many other services similarly transformed how care was delivered and the utilization of those services.

The Medicare program is at another critical policy juncture. Under PPACA, Medicare reimbursement will move away from the current system of volume-based payment for individual patients to one that will be quality-based for a defined population. Programs like the CMS quality incentive programs, Accountable Care Organization program and payment bundling are designed to incentivize providers to deliver services in a more efficient and effective manner. The exact form these new systems will take and the downstream impacts of these changes are difficult to predict; however, there will be significant changes to traditional relationships between hospitals, physicians, and other providers with the intent to be more aligned rather than fragmented as facilities and health care professionals form integrated systems to deliver patient centered care. The demand for services will be altered, as will the resulting need for facilities and service providers.

During this transformation period, CON regulations will provide an important source of stability and predictability for providers as they seek to participate in these advanced delivery models, especially those requiring the assumption of financial risk for the health of a given population. Absent CON regulation, there would be rapid proliferation of new providers, particularly for services that offer the greatest profit potential. This would result in further fragmenting the delivery system and work against the goal of integration. Existing providers, particularly hospitals, which are at the forefront of health care delivery reform, would face declining volumes and financial performance at the precise time that they would be making substantial investments in these new delivery models. Providers would be reluctant to participate in bundled payment demonstration projects if there is no CON because the healthier, better insured patients could be

diverted to new freestanding facilities while hospitals would be providing services for the sickest, higher acuity patients, which would significantly increase their assumed risk.

A significant caveat is the uncertain future direction of Health Care Reform. With the results of the recent Congressional elections, it is possible that PPACA could be significantly changed. It would be premature to alter Kentucky's CON program now when the long-term structure of this effort is in a state of flux.

The expansion of Kentucky's Medicaid Program and the shift to a Medicaid Managed Care model are a part of the evolving delivery system. KHA is supportive of CHFS' efforts to control the Medicaid budget and create a program that can sustain itself over the long term. Medicaid recipients, however, remain a smaller portion of most providers' patient base in comparison to Medicare, and changes in Medicaid policies will not impact providers' behavior to the same extent as the steps taken by Medicare. Moreover, the reduction or elimination of CON regulations will likely create further challenges for Medicaid recipients to access care.

Based on the experiences of other states, the growth in facilities and services that will come from deregulation of CON will be by organizations seeking to serve commercially-insured patients, not Medicaid and indigent patients. If hospitals, which are the primary providers of Medicaid services, lose these commercial insurance patients, their ability to continue to provide care to Medicaid and indigent patients will be reduced. This problem will be most significant for rural hospitals that bear proportionally high loads of Medicaid and indigent patients and whose very existence will be threatened by the loss of their relatively few higher margin patients to new competitors.

Many states that were early adopters of health reform maintain CON regulation. Massachusetts, which was the model for the federal Health Care Reform legislation and has opted to expand its Medicaid program under PPACA, maintains an active "Determination of Need" process that is considerably more complex than Kentucky's program. Maryland, which has been at the forefront of efforts to change payment approaches for Medicare, as well as other payers, also maintains stringent CON regulations. West Virginia also is another state that elected to expand Medicaid coverage, and its CON program continues unchanged.

For these reasons, CON deregulation in Kentucky will have the opposite effect of supporting health care transformation and only a limited, if any, impact in addressing the other core principles that CHFS has set forth in its Memorandum.

- Supporting the Evolution of Care Delivery – The evolution in health care delivery that is at the heart of Health Care Reform is not frustrated by CON regulation. The focus of these new models is altering payment incentives, which are independent of CON regulations. However, the new payment models, which will likely bundle payment and require providers to take more risk for managing population health, will necessarily require greater integration of services and providers. Last year, KHA and its members engaged the national consultants of Dobson/DaVanzo and Milliman to undertake a study which yielded strategic recommendations for future changes to prepare hospitals to move toward payment for value and population health management. These recommendations included:

- Building clinically integrated networks with other providers to manage care, with an emphasis on primary care physicians and mental health professionals;
- Obtaining claims data from all sites of service to better understand utilization of health care services, particularly among the Medicaid population, needed to develop and target strategies to shift care, where clinically appropriate, to lower cost settings and enable hospitals to enter into risk sharing arrangements with payers;
- Expanding access to primary care, such as through medical homes, to manage patient care and reduce unnecessary emergency room utilization;
- Developing a uniform set of performance measures for hospitals; and
- Moving toward risk sharing through upside risk arrangements (shared savings, gain-sharing) in future years and in tandem with changes in federal reimbursement programs.

These recommendations recognize that the future direction will require a greater focus on assuring access to primary care and an array of services to assist patients in managing chronic conditions so as to avoid the need for acute inpatient care. Maintaining the CON program does not conflict with, and in fact supports, this new direction.

Kentucky's existing CON program already exempts or applies a minimal review standard to most outpatient services. Most primary care services - where expansion is needed - are not even subject to CON. Kentucky's CON law exempts primary care centers, rural health clinics, special clinics and other clinics which only provide diagnostic services with equipment not exceeding the cost threshold or which are addressed in the State Health Plan. Other types of outpatient centers, such as ambulatory care centers, outpatient rehab centers, limited services clinics, and behavioral health services organizations all qualify for expedited review through the nonsubstantive review process where applications are given a presumption of need. Indeed, Kentucky's formal review process has been reserved for those services and facilities which involve high cost and for which volume is frequently related to assuring quality of care. For these services, such as inpatient beds, high cost equipment, and surgical services, unnecessary duplication could result in excess capacity which would have to be paid for as well as the potential for unnecessary utilization due to physician self referral in the absence of a CON program which ties service growth to the population's unmet need. Thus, KHA does not believe any changes to Kentucky's CON program are necessary at this time to accommodate movement to new delivery models.

- CON deregulation at this time and under current payment conditions would result in greater fragmentation rather than enhancing the integration of care.

  Kentucky's CON standards have evolved over time to accommodate changes in care delivery and clinical guidelines. One example is the adoption of new standards that allow hospitals without open heart surgery backup to provide primary Percutaneous Coronary Intervention ("PCI") once research demonstrated the effectiveness of such programs in reducing mortality for cardiac events. Recently, the CON standards for Neonatal Intensive Care ("NICU") services were modified to permit better distribution of Level III NICU programs across the Commonwealth. Because the State Health Plan is updated annually, any future needed changes to CON regulations can be enacted as Health Care Reform unfolds.

- Incentivizing Development of a Full Continuum of Care – The development of a full continuum of care is precisely the objective of ACOs and similar delivery models that are evolving. The creation of such delivery systems is not adversely impacted by Kentucky's CON regulations. In most parts of Kentucky today, there is sufficient availability and capacity of health services to allow new models of care to be developed without allowing unchecked proliferation of new services and facilities. The incentives to develop a full continuum of care will be driven by payment systems and the needs of the populations served. A clear example of this is the Cabinet's own action to alter the Medicaid program not only to cover a broad array of outpatient behavioral health and substance services, but to open up the network where providers other than community mental health centers can now offer these services. These actions will increase access to a full continuum of behavioral health services and required no changes to CON. However, as mentioned above, CON deregulation could destabilize the overall delivery system and further fragment services which would deter, rather than encourage, clinical integration and the financial ability of hospitals to begin to share risk for population health management.

- Incentivizing Quality – Quality of care will be a function of the care management systems implemented by organizations. CON deregulation would likely have the effect of diminishing quality of care by reducing volumes across all providers and stretching scarce resources over a greater number of providers. CON standards currently support quality because CON criteria seeks to ensure that new facilities operate at volumes that are sufficient to provide quality services as well as assuring that new volume does not come at the expense of existing providers where the lowering of their volumes could reduce quality of existing programs. ACOs and similar organizations are likely to concentrate services in fewer facilities to enhance both quality and operational efficiency, which is consistent with the CON standards in place.

- Improving Access to Care – As noted above, CON deregulation could have the effect of reducing access by destabilizing local health care systems. Smaller, rural hospitals in particular are vulnerable to the loss of profitable patients to private organizations that would be developed without CON standards in place. These rural hospitals are a critical point of access for many Kentucky residents. Similarly, the exodus of higher margin patients from safety-net hospitals will adversely affect their ability to fund the many unprofitable services they provide to meet community needs. In addition, new services developed in the absence of CON tend to be located in more affluent areas to serve commercial patients and not Medicaid or other low income patients. Thus, deregulation of CON will not serve to increase access for the Medicaid population and could actually worsen the access challenges these patients already face.

- Improving Value of Care - There is no evidence the states without CON programs offer higher value care. To the contrary, in most cases, states without CON have significantly greater duplication of resources and operate on average at lower volumes per provider. The notion that freestanding providers such as ASCs provide lower cost and greater efficiency, as will be discussed with respect to the Deloitte Report, is not accurate when viewed in the context of the larger delivery system. The proliferation of freestanding facilities can ultimately result in unnecessary utilization and lower quality while at the same time destabilizing providers that address the broader needs of the community. The Cabinet's CON

Modernization principles mentioned incentivizing price transparency through CON, yet this is misplaced since other forces unrelated to CON are already addressing transparency. Kentucky hospitals have long supported making price information available to consumers and, in 2005, KHA voluntarily posted prices by hospital for the top DRGs on a public website. Price transparency for hospitals is now statutorily required by the ACA and KHA now posts hospital prices for every DRG on its public website and is actively working to expand this information to include outpatient procedures. However, patients rarely "shop" for inpatient care and today are increasingly restricted to obtain care within a defined provider network. Consumers are more interested in their own cost sharing, which is dependent on their insurance plan. Thus, while consumers will no doubt have access to more information on pricing, changes to CON are not needed to accomplish this.

- Promoting Adoption of Efficient Technology – There is simply no relationship between the adoption of efficient technology and CON regulation. Administrative and clinical information systems are not subject to specific CON regulations in Kentucky. With the exception of a few high dollar types of equipment, hospitals and other providers are able to acquire new equipment without CON review for items below the capital expenditure threshold. Replacement of outmoded equipment above the threshold is subject to nonsubstantive review. Policies already in place will drive the adoption of new technology such as the Center for Medicare and Medicaid Services' (CMS) meaningful-use regulations that impose reductions in Medicare reimbursement on providers who fail to meet specified targets for implementation of electronic health records and standards for electronic transfer of clinical information. KHA does support the ability of providers to have greater access to data to better understand utilization patterns of specific populations as we move toward population health. Rather than focusing on building an all payer database across all services, which could be very time consuming, KHA encourages the Cabinet to begin by sharing with hospitals data they already have. This should include timely Medicaid claims and encounter data, as CMS does on a more delayed basis, to enable hospitals to move toward shared risk arrangements and population health management.

- Exempting Services for Which CON is No Longer Necessary –There are no services that the Deloitte Report recommended for elimination of CON review that would appropriately be deregulated. The concern with ensuring sufficient capacity in the future to accommodate a growing base of insured Kentuckians is not based on objective analysis. There are no capacity issues or other considerations that would require the elimination of CON to ensure adequate availability of care. The impact on rural hospitals and safety-net hospitals must also be considered when exempting services from review, and such changes could challenge the ability of these providers to offer the same level of access in the future. It is premature today to make changes that will result in greater fragmentation rather than integration of providers. The CON program should be continually reviewed, as it has been, and revised in accordance with health planning principles which consider actual changes in the delivery system and data documenting needs and gaps in services.

History and Evolution of CON Regulation

The purpose of the Kentucky Certificate of Need law, as expressed in KRS 216B.010, is "to improve the quality and increase access to health-care facilities, services, and providers, and to

create a cost-efficient health-care delivery system for the citizens of the Commonwealth." The General Assembly noted that the "proliferation of unnecessary health-care facilities, health services, and major medical equipment results in costly duplication and underuse of such facilities, services and equipment and that such proliferation increases the cost of quality health care within the Commonwealth." KRS 216B.010.

The Kentucky CON statutes were first enacted in 1972. The National Health Planning Resources Development Act of 1974 (PL 93-641), required each state to adopt a health planning structure and CON review criteria, and providers were required to apply for a CON before undertaking major capital expenditures or implementation of certain specialized services. The development of Kentucky's CON program and State Health Plan criteria closely paralleled the national standards. All states except for Arizona ultimately adopted CON programs.

Over time, the federal government relaxed requirements for CON review in states and by the mid-1980s, several states, most located west of the Mississippi River, eliminated or substantially reduced CON review. The federal mandate for CON review was formally repealed in 1987, and 14 states eliminated their CON programs, and 36 states, as well as Puerto Rico and the District of Columbia, maintain programs today, although of scope of these programs differs materially. Kentucky's CON review program has undergone numerous changes over the years.

Research on the Effectiveness of CON Regulation

The efficacy of CON regulation has been debated over the years in many states, including Kentucky, and by a variety of researchers and agencies. The fundamental issue is whether regulatory models can offer a better means of distributing health care services than a competitive, free-market model. Given that several states have eliminated CON regulation entirely, there is some data available to evaluate the impact of deregulation. Given the dramatic differences among states in geography, demographics, economic environment, and availability of health resources, the lessons from one state may not be directly transferable to another.
Figure 1 summarizes the key arguments for and against continuation of CON regulation.

Figure 1
The Debate over CON Deregulation

Criticisms of CON Regulation	Support for CON regulation
CON has failed to control health care costs, one of its primary purposes. In fact, the CON process imposes additional, unnecessary costs on providers.	CON programs have reduced the level of unnecessary duplication in health care services. By constraining the development of unneeded and unused capacity, existing providers can operate more efficiently.
A competitive system relying on market forces will result in a more efficient allocation of health care services than regulation.	Health care is different from other elements of the economy. Consumer behavior is not generally influenced by the price of health services because payment is typically made by insurers. The complexity of medical care makes it difficult for consumers to differentiate among providers on the basis of quality.
The CON process protects existing providers and stifles innovation.	CON regulation does permit competition when effectively implemented. Decisions necessarily must consider the broader context of how approval of a new program or facility will affect the ability of existing providers to continue needed services.
The Kentucky CON hearing process is too costly and lengthy and delays the implementation of needed services and facilities.	The Kentucky CON hearing process is significantly less complex, time consuming, and costly than many other states.
There is no evidence that quality is higher in states that have CON programs compared to states without CON. Enhanced competition will require providers to raise quality levels to compete effectively.	There is ample evidence in the literature regarding the relationship between the volume of procedures performed by providers and the outcomes patients achieve. Limiting the number of providers, particularly of tertiary services, can result in better health outcomes.
CON regulations and decisions can be influenced by political manipulation.	The checks and balances in the CON hearings process, with an administrative law judge issuing decisions, minimize the potential for politically motivated decision-making.
There is no evidence that access to care by Medicaid and charity patients is negatively affected by the elimination of CON. Federal and state laws require hospitals, for example, to accept patients requiring emergent treatment. States that have deregulated continue to meet the needs of patients without financial means. The Patient Protection Act and Medicaid expansion will reduce the number of uninsured in the future.	Kentucky has seen its uninsured population decline but has an expanding pool of Medicaid recipients. New providers will likely focus on the most profitable patients. There is strong potential in an unregulated market for key safety net hospitals in Kentucky to be substantially harmed financially, by the loss of better insured patients thereby limiting their ability to serve disadvantaged groups.

In exploring the arguments for and against CON, it is important to move beyond the academic debate and address this basic question:

Will the elimination of the Certificate of Need (CON) regulations in Kentucky have a positive or negative impact on cost, quality, and access of health care services?

This paper will consider the answer to that question based on the following considerations:

- Cost of health care services
- Quality of care
- Access to care
- Competition
- Cost and fairness of Kentucky's CON process

1. CON Regulation and the Cost of Health Care Services

There have been a number of studies over the years that have addressed the issue of whether CON programs control health care costs. These studies have produced conflicting results, although there is no clear evidence of CON deregulation resulting in lower costs, either in total health expenditures or hospital expenditures.

Cleverly & Associates[2] performed a comparison of hospital costs and payer mix in CON regulated states and non-CON regulated states in conjunction with the Georgia Legislature's consideration of CON deregulation. In the report, Dr. Cleverly concluded:

- Total hospital costs for producing equivalent case-mix-adjusted inpatient and outpatient services are lower in CON states compared to non-CON states.

- Actual levels of profitability in CON states are significantly lower than those of all non-CON states.

- Actual payments on a case-mix adjusted basis are lower in CON states when compared to non-CON states.

- The total level of payments from both public and private payers for equivalent case-mix-adjusted services are lower in CON regulated states when compared to the non-CON states.

Conover and Sloan[3] conducted one of the most comprehensive reviews of the research literature on this topic and noted that, while other studies had advocated prospective payment systems or government rate setting as superior strategies to CON, "the other programs became worse performers in terms of cost containment as the provider community became more familiar with them." This finding by Conover and Sloan is an important point because CON offers the

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[2] Cleverly & Associates, "An Analysis of Hospital Costs and Payer Mix in CON and Non-CON States," a report prepared for presentation to the Georgia Legislature, November 2006.

[3]Conover, C.J. and Sloan, F.A. "Does Removing Certificate of Need Regulation Lead to a Surge in Health Spending?" *Journal of Health Care Politics, Policy and Law*, Vol. 23, No. 3, June 1998.

potential to reduce the proliferation of unneeded services and the inherent duplication of capital and operating costs that excess capacity generates.

What none of the studies have focused on is the cost to the system when safety-net and rural hospitals suffer significant losses of patients and revenues due to reduction in volumes that result from a growing number of competitors. Eliminating CON regulation does not address in any way the problem of meeting the health care needs of uninsured and indigent patients or ensuring access to rural communities. Moreover, it does not address the problems that the expanding pool of Medicaid patients in Kentucky faces in accessing care. CON deregulation will result in more investor-owned companies entering Kentucky seeking to serve patients covered under commercial insurance plans, which will divert needed revenues away from hospitals who serve the patients with the greatest barriers to care.

If the finances of safety-net or rural hospitals become unstable due to a rapid increase in competition, who will meet these needs? Kentucky and many other states already struggle with controlling Medicaid budgets. If the costs of serving the uninsured and Medicaid patients are no longer borne to a large extent by safety-net providers, how will these costs be funded? These questions must be answered before any decisions are made to change Kentucky's CON program.

The Federal Trade Commission and the Department of Justice[4] issued a joint report in 2004 recommending increased competition as a means of improving health care delivery. Among the recommendations made by the DOJ/FTC were:

> *States with Certificate of Need programs should reconsider whether these programs best serve their citizens' health care needs*
>
> *The Agencies believe that, on balance, CON programs are not successful in containing health care costs, and that they pose serious anticompetitive risks that usually outweigh their purported economic benefits...Other means of cost control appear to be more effective and pose less significant competitive concerns.*

The American Health Planning Association, however, challenged this DOJ/FTC recommendation pointing out a number of factors that illustrate the shortcomings of an open market model of health care.[5] Among these factors are:

- Capital costs in health care are passed on to consumers.
- Consumers do not and cannot "shop" for health care based on price and quality since information is often unavailable or ambiguous.
- Adding additional providers in a market can increase demand for health care services and increase capacity to serve them.

[4] "Improving Health Care: A Dose of Competition," A Report by the Department of Justice and the Federal Trade Commission, July 2004.
[5] Piper, T.R., "Certificate of Need: Protecting the Public Interest," Presentation to the Missouri State Senate Interim Committee on Certificate of Need, August 1, 2006.

- Studies by the "Big Three" automakers have found that their health benefit costs are substantially lower in CON-regulated states than in non-CON states.

A recent study examining cost data from 37 states with and without CON programs found: "Average estimated cost-inefficiency was less in CON states (8.10%) than in non-CON states (12.46%). Results suggest that CON regulation may be an effective policy instrument in an era of a new medical arms race. However, broader analysis of the effects of CON regulation on efficiency, quality, access, prices, and innovation is needed before a policy recommendation can be made."[6]

The lack of consensus about the cost impact of CON is due in part to the inherent difficulties in comparing "costs" or "prices" between states or even markets within states.

- *Gross charges or prices are not a meaningful indicator of health care costs.* Few patients pay the nominal prices that providers charge. Managed care organizations negotiate discounted rates and governmental programs; such as Medicare and Medicaid, dictate the rates that they will reimburse.

- *There is no readily available data on net prices paid by third party insurers.* Because of competitive pressures, insurers do not issue data with respect to amounts paid to individual providers for specific services.

- *Data on costs and charges are not available for all providers.* Over the last two decades, a growing percentage of health care expenditures occurred outside of the hospital setting. While data are generally available from hospitals, there is limited reporting of cost and charges by other providers such as private physician practices, freestanding ambulatory care centers, and imaging centers. In measuring changes in health care costs or prices, there is no means of capturing a comprehensive profile of all segments of the industry.

- *Collecting comparable data is difficult.* Costs and charges are influenced by a number of factors such as local economic factors, mix and severity of cases, managed care penetration, and payer mix. While there are methodologies to adjust charges and costs in an effort to normalize them for comparative purposes, there are inherent limitations with such methodologies.

As a consequence, it is not surprising that different researchers reach different conclusions about the cost effectiveness of CON regulation. There is little question, however, that the removal of CON regulations in Kentucky will result in greater duplication of existing facilities and services and diminished volumes for existing providers. The higher costs associated with such a change will either be borne by payers and consumers or the financial viability of many existing providers will be threatened.

[6] Rosko, Michael D. and Mutter, Ryan L., "The Association of Hospital Cost-Inefficiency With Certificate-of-Need Regulation," *Med Care Res Rev*, June 2014, vol. 71 no. 3 280-298.

2. The Experience of Other States

The often-expressed belief that the elimination of CON regulation results in more choices, improved access, and lower costs has not been borne out by actual experience. Other states that have repealed CON, such as Ohio, have seen significant changes in the composition of their health care system. Ohio began its deregulation process in 1995. By 2001, 11 inner-city hospitals in Ohio had closed, along with 6 rural hospitals. There were 19 new acute care hospitals developed during this period, but these were primarily long-term acute care and specialty hospitals.[7] In addition, there was:

- 137% surge in outpatient dialysis stations
- 600% increase in ambulatory surgical centers
- 548% jump in freestanding MRIs
- 280% increase in radiation therapy.

Pennsylvania allowed its CON statute to sunset in 1996. Since that time, the number of new providers, including imaging centers, specialty services, and ambulatory surgery centers, has increased dramatically, and the growth of services and technology has resulted in increased utilization and spending.

- Since 2000, the number of ambulatory surgery centers licensed in Pennsylvania has risen from 104 to 245.
- Forty-eight of those centers opened during the same year and patient visits during that period jumped 83%.
- Pennsylvania's ambulatory surgery utilization rates are 36% higher than the national average.
- Visits to ambulatory surgery centers increased 83% from 2001 to 2003.
- Legislation to reestablish CON has been introduced in both the Pennsylvania House and Senate.[8]

Indiana completely repealed its CON program in 1996, briefly reinstated it from 1997 to 1999, and then permanently repealed it in 1999. ASCs were not regulated in Indiana so the repeal of the CON law primarily resulted in an increase in hospital facilities, in specialty hospitals, particularly psychiatric hospitals, most which closed over the next decade. Indiana has attempted other legal measures to keep specialty hospitals for women and cardiac care locally owned with varying degrees of success.

Texas is perhaps the most deregulated of all states with respect to the development of health care services and facilities. Texas providers seeking to establish new facilities and services are subject to little oversight. For example, currently there are 442 ambulatory surgery centers in Texas. The majority of these centers are owned by physician or private investor groups.[9] In addition, there are 122 freestanding emergency departments, the bulk of which are operated by physicians or investors who see the ability to bill for higher reimbursement as an ED rather than as an urgent

[7] McBeath, Gretchen, "Status Report on Ohio After Deregulation from Certificate of Need," internal publication of Bricker & Eckler, September 2001

[8] "South Carolina's Certificate of Need Program," South Carolina Hospital Association, January 2012.

[9] Texas Department of State Health Services Directory

care center.[10] There are 62 birthing centers in the state, all for-profit organizations operated by a mixture of physicians, mid-wives, and private corporations. There have been investigations in recent years of hospitals and freestanding emergency departments with serious quality issues operated by unqualified individuals.

What is clear from these examples is that elimination of CON regulation will stimulate growth in services and facilities that hold the greatest profit potential. There is no ability to ensure the appropriate distribution of services or that patients facing access barriers (e.g., uninsured, Medicaid, rural residents) continue to have access to needed care. Moreover, safety-net providers in these states have seen commercial insurance revenues decline as they assumed the burden of caring for the underserved population.

3. CON Regulation and the Quality of Health Care Services

There is a significant body of research demonstrating that the quality of patient outcomes is related to the volume of procedures performed, particularly for more complex procedures that are relatively infrequently performed. There is strong potential for quality to suffer if the numbers of providers increase for CON covered services and existing volume is distributed across a greater number of providers. The experience of other states that have eliminated CON regulation has been rapid and dramatic expansion of the number of providers offering services such as open heart surgery, interventional cardiac catheterization, and neonatal intensive care. In contrast, the Kentucky CON program relies on population-based need projections and minimum volume standards adapted from accepted published research to support approval of a new program or facility.

The most recent statement from the American College of Cardiology Foundation/American Heart Association/American College of Physicians Task Force on Clinical Competence and Training regarding coronary artery interventional procedures concluded: "The relationship between quality and volume in cardiac procedures is well-established. Overall, the preponderance of data suggests that hospitals in which fewer coronary interventions are performed have a greater incidence of adverse events, notably death and CABG surgery for failed intervention, than hospitals performing more procedures. This relation is supported by earlier studies in the percutaneous transluminal coronary angioplasty (PTCA) era, contemporary studies in the stent era and a recent meta-analysis."[11]

While seeking to maximize quality, Kentucky's CON program has sought also to ensure appropriate access to specialized services. For example, CHFS has adopted CON standards that allow hospitals to participate in a pilot study to perform primary and elective percutaneous coronary interventions (PCIs) without open heart surgical back-up. If the pilot program satisfies certain criteria after two years, it may apply under nonsubstantive review to operate the program permanently. Such a program recognizes circumstances where approval of a new program may be granted that might otherwise not meet established volume requirements but not allow the wholesale proliferation of programs that would result in poorer clinical outcomes.

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[10] Kaiser Health News, July 15, 2013.

[11] Harold, John G., et al., " ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures," *Journal of the American College of Cardiology*, Vol. 62, No. 4, 2013.

A study published in the New England Journal of Medicine[12] examined the performance of neonatal intensive care units (NICU) in treating the very-low-birth-weight infants who have some of the most severe conditions that these units serve. The conclusion of this study was that "[m]ortality among very-low-birth-weight infants was lowest for deliveries that occurred in hospitals with NICUs that had both a high level of care and a high volume of such patients. Our results suggest that increased use of such facilities might reduce mortality among very-low-birth-weight infants."

Simple elimination of CON raises significant concerns about ensuring quality standards for the services covered under the State Health Plan today. In the case of certain tertiary services, which may or may not continue to be regulated, e.g., organ transplantation, open heart surgery, there are demographic and structural factors that limit the number of procedures that can be performed each year. In addition, there are significant infrastructure costs associated with these highly specialized programs. The proliferation of tertiary services could result both in a reduction in quality and greater financial losses by providers if small volumes of cases are spread over an increasing number of programs.

Another consideration is the impact of CON deregulation on the quality of medical education. In order to maintain accreditation of residency and other training programs, certain volumes of specialized services must be maintained. If tertiary patients are redirected from teaching and tertiary hospitals to community hospitals, the ability of trainees to gain sufficient clinical experience will be challenged.

4. CON Regulation and Access to Health Care Services

A common criticism of CON regulation is that it restricts access to health care services by constraining the numbers and locations of health care services and facilities. Situations such as overcrowded emergency rooms seem to point to the need for greater capacity. As discussed above, the elimination of CON regulation does result in a short-term surge in health care spending, but mere expansion does not ensure that access is maintained or expanded for all citizens.

Geographic Access

For states that have eliminated or substantially reduced CON regulation, geographic access to care has not uniformly improved. Much of the new development focused on new facilities or services in affluent suburbs of metropolitan areas. Inner cities and smaller rural communities were not desirable markets for organizations seeking to expand. In some cases, the lack of CON regulation resulted in the development of facilities such as ambulatory surgery centers and outpatient diagnostic centers in smaller communities that severely impacted the financial stability of hospitals serving those communities and resulted in hospital closures. In the absence of regulations to ensure the appropriate distribution of health care facilities and services, the likelihood is that services will cluster around high population, high income areas and smaller communities will see access reduced.

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[12] Phibbs, C.S. et al., "Level and Volume of Neonatal Intensive Care and Mortality in Very-Low-Birth-Weight Infants," *New England Journal of Medicine*, Volume 356:2165-2175, May 24, 2007

Rural hospitals are already threatened by declining reimbursement and limited capital to invest in new facilities, services, and physician recruitment. The North Carolina Rural Health Research Program tracks hospital closures and since 2010, 43 hospitals across the country have closed and 27 of these were located in rural areas.[13] Only one of those facilities was in Kentucky. Another 8 hospitals that closed were located in Micropolitan Statistical Areas, and only 8 were in Metropolitan Statistical Areas. Elimination of Kentucky's CON regulations for key services could accelerate the closure of rural hospitals and the loss of geographic access for the communities they serve.

Safety-net hospitals provide a disproportionate level of uncompensated care compared to other facilities. In recognition of this fact, these Disproportionate Share Hospitals ("DSHs") receive Disproportionate Share payments from CMS to help offset the cost of caring for large numbers of Medicaid, Medicare, and uninsured patients. One component of PPACA calls for DSH payments to be significantly reduced over a period of years. The underlying assumption for this change is that the expansion of Medicaid coverage would reduce the number of uninsured individuals that, in theory, would leave lower levels of uncompensated care costs. However, the Kentucky Medicaid program covers, on average, only 82% of actual inpatient and outpatient hospital costs of providing care to Medicaid patients, leaving a substantial unpaid shortfall that will grow considerably with Medicaid expansion. In addition, hospitals have rising uncompensated care costs from the Medicare program due to payment reductions under the ACA, as well as from rising bad bets as more insured individuals and families are unable to pay higher deductibles and copayments. In fact, when the total impact of the ACA is considered, overall Kentucky hospital payment reductions from both the Medicare and Medicaid programs are projected to exceed the additional revenue from the newly insured (most of whom are on Medicaid) by nearly one billion dollars over the first ten years of the ACA. The loss of commercial insurance patients to new providers that would enter urban markets following CON deregulation would exacerbate the financial problems faced by these hospitals and require either additional public subsidies or service reductions.

Financial Access

One major barrier to access is the financial status of residents requiring care. Numerous studies have demonstrated that individuals without health insurance or other means to pay for care utilize health care services at much lower rates. Similarly, patients who qualify for Medicaid face barriers to access in part due to the reluctance of certain providers to treat Medicaid recipients due to the relatively low rate of reimbursement by the Medicaid program.

While Kentucky's uninsured population has been reduced due to Medicaid expansion, the adoption of a Medicaid managed care model has resulted in providers receiving lower Medicaid reimbursement and a much more onerous process to get services approved and to just get paid. Medicaid is not the most desirable payer group for providers and, based on the experience of other states where CON regulation has been eliminated, new providers entering the market will likely target better paying populations leaving the sicker, less well-insured patients to community hospitals and teaching institutions. While hospitals have always accepted patients regardless of their payer source or ability to pay, other providers have not always shared that same

[13]North Carolina Rural Health Research Program: http://www.shepscenter.unc.edu/programs-projects/rural-health/

commitment to financial access, and that inequity between hospitals and other providers would only be exacerbated without CON.

5. CON Regulation and Competition

There is little question that the elimination of CON will result in a greater number of competitors entering the market. As discussed above, health care services do not fit neatly into a competitive market model because consumers are insulated from the price of services by insurance companies, and it is difficult for consumers to differentiate among providers on the basis of quality and cost even with the growing level of quality data becoming available. It is important to ask: How will Kentuckians specifically benefit from the enhanced competition that will result from CON deregulation?

1. Will consumers experience lower prices? – There is no simple answer to this question. First, the prices paid on behalf of consumers by Medicare, Medicaid, CHAMPUS, and other governmental payers, which represent approximately 50% percent of total patient charges in Kentucky hospitals, will not be affected by enhanced competition since these rates are set by regulation. In fact, the costs to the Medicaid program could increase if rural and safety net hospitals require a government subsidy to offset lost revenue from commercial patients which are singled out by new competitors in order for those facilities to remain viable and continue providing essential services to their communities and Medicaid patients in particular. Also, if new competitors result in lowering the payment for a particular service offered by hospitals, the prices for remaining hospital services would necessarily have to rise to cover overhead costs required to maintain the facility and access to remaining services. Thus, in the end, such "competition" can serve to increase overall health care costs.

   Another consideration is a significant increase in the number of providers could result in higher prices unless volume growth accompanies new investment in services and facilities. As will be discussed below with respect to ambulatory surgery centers, expansion of unneeded facilities can result in unnecessary utilization of these services as new operators seek to justify their investments. This is particularly true if the owners of new services are physicians which can self refer patients to these services. If existing providers see declines in volume due to new competition, they will be forced to raise prices to cover the fixed costs of operation.

   The pricing issue is further complicated by the trend for insurance plans to impose higher deductibles and coinsurance on insured members. Patients are indifferent to the price that their insurance companies pay, but they are highly sensitive to their own out-of-pocket expenses. As an example, in the Owensboro area new ASCs have opened across the Ohio River in Indiana, which does not have CON regulation. These providers are not in the Owensboro insurance network. Patients will seek services there because of doctor referrals and the promise of lower co-payment. Because the ASC is not in the network, payment is based on the facility's charge rather than a negotiated rate. As a result, the total price paid for the outpatient surgery, including the patient's co-payment and the insurance company's payment to the facility, is higher than if the patients had received in-network services in Kentucky. Ultimately, this higher cost is borne by the patient's employer in the form of higher insurance premiums in the future.

2. Will competition result in improved quality? – There is no evidence in the literature that quality of care in states without CON regulation is higher than in states with CON. As discussed previously, there are numerous studies that link quality and volume in certain services. Spreading the volumes of these services across more facilities could result in decreases in quality in the long-run.

3. Will competition enhance accessibility of services? – Improvements in access are only necessary if access problems exist today and new services developed are located in these areas of need. The experience of other states without CON is not that underserved areas receive needed services, but instead, that new service development occurs in areas that already have access to care but represent a higher potential for profit. New entrants to a market also rarely serve Medicaid patients – a population where access is already a challenge. In fact, access in rural areas and for Medicaid patients could be threatened with greater competition unless other measures – such as higher reimbursement or government subsidies - are implemented to support rural and safety-net hospitals.

   Kentucky already permits significant competition even under CON regulation. There are numerous providers across the spectrum of services that Kentucky's CON program regulates. In situations where existing providers are not addressing community needs, new competitors can be approved under existing CON standards

6. Cost and Fairness of Kentucky's CON Program

Kentucky's CON program does not impose more stringent restrictions on the development of new services in comparison to other CON states. According to a comprehensive survey of state CON programs undertaken by the American Health Planning Association in 2011, Kentucky regulated 18 distinct services, which placed it toward the middle of states with active CON programs, as summarized in Figure 2. Attached, as Appendix A, is the complete summary prepared by the American Health Planning Association which compares the scope of CON programs across the country.

Kentucky's CON program has the ability to be changed or amended as needed and has changed considerably over the years as conditions were appropriate to make a change. Several services, such as CT scanners and lithotripters, have been exempted from CON review. Currently, only inpatient beds, high cost services, and services where there is a safety or quality issue are still required to go through a formal review process.

Kentucky also allows for many projects to be submitted under a nonsubstantive review process, which has an expedited review period and a presumption of need that anyone challenging the application must rebut. Most outpatient services require only nonsubstantive review. Other examples of nonsubstantive review projects include change in the location of a proposed health facility, replacement or relocation a licensed health facility (if there is no substantial change in health services bed capacity), transfer of beds (excluding Level III neonatal intensive care beds) between licensed health care facilities, replacement or repair of worn equipment if the worn equipment has been used by the applicant in a health facility for five (5) years or more, and cost escalations of previously granted CON projects, among others. Health care facilities are allowed

to incur capital expenditures or purchase major medical equipment for amounts up to approximately $2.9 million without having to seek CON approval.

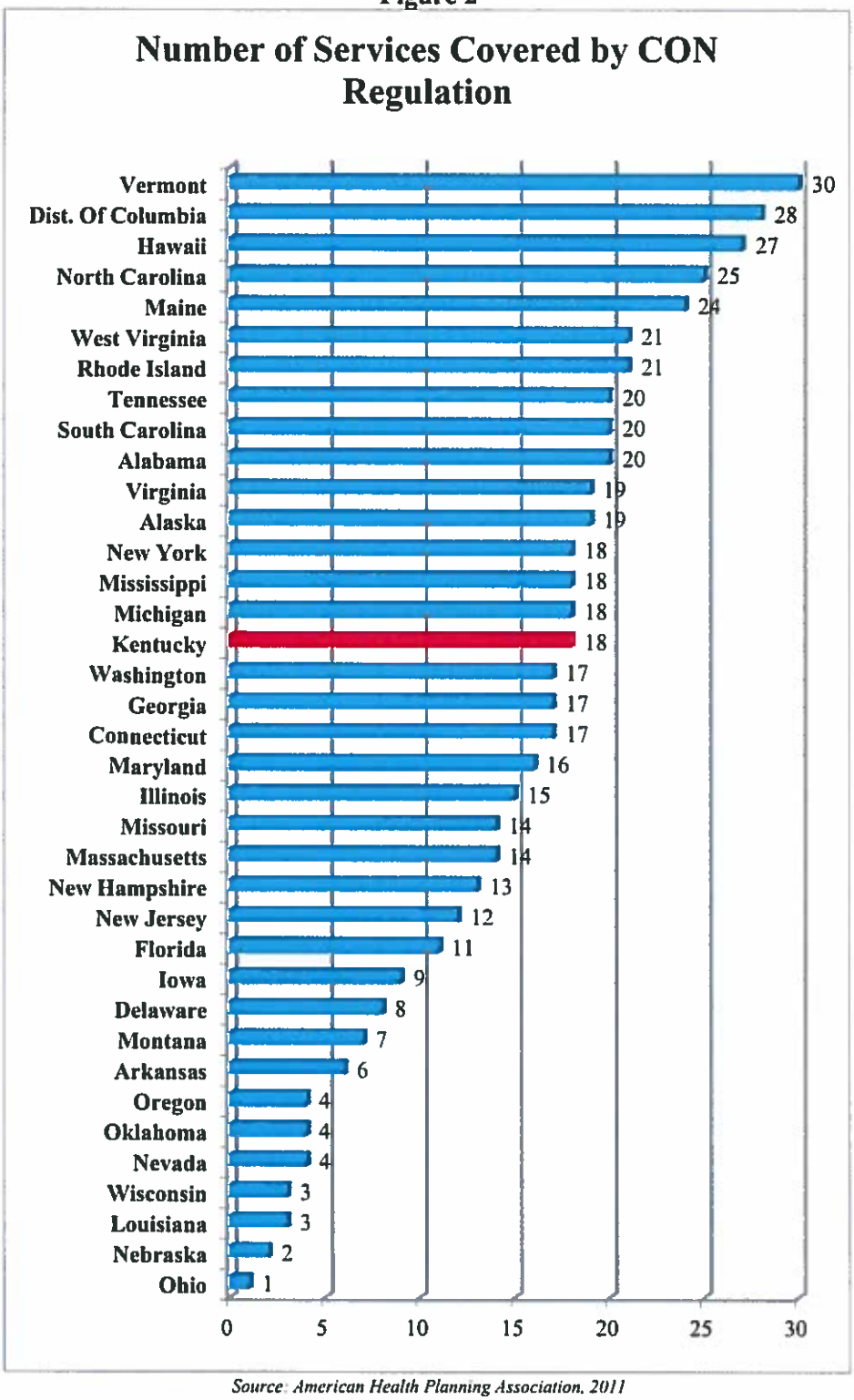
Kentucky's CON application filing fees are reasonable in comparison to other CON states. Kentucky's maximum filing fee for a substantive review application is $25,000. States such as Florida, Georgia, and West Virginia have maximum filing fees of $50,000.

Kentucky applicants have considerably more latitude once an application has been filed to defer consideration of the application and to amend the application, within certain limitations, at an administrative hearing. In many other CON states, applications are reviewed according to rigid batching cycles without the possibility of deferral or amendment once the application is deemed complete.

Kentucky's administrative hearing process is significantly less burdensome than other states. Kentucky is most similar to Alabama, Mississippi, and West Virginia in that administrative appeal hearings are held before the initial agency decision is rendered. Kentucky limits discovery prior to a hearing and depositions of witnesses are rarely taken. Kentucky hearings typically last two to three days. Decisions by administrative law judges are due by specified dates unless the decision deadline is waived by the applicant. In most cases, Kentucky applicants can expect to receive a decision within the standard review cycle deadlines even when administrative hearings are required. Despite the similar approach, the hearing processes in Alabama, Mississippi, and West Virginia are far less efficient. The scheduling of hearings often occurs many months after an initial hearing request is filed and there are often lengthy delays in the issuance of the hearing officer's decisions and the final agency action on the application.

Other states such as Florida, South Carolina, and North Carolina do not schedule an administrative hearing until after the CON agency issues its initial decision. These states permit substantial pre-hearing discovery, witnesses listed by parties are subject to often lengthy depositions, and the initiation of hearings is often delayed for four to six months after the initial decision. The hearings sometimes require multiple weeks for completion. Administrative law judges have more flexibility in the time to render decisions, which often occur many months following the completion of the hearing. A delay of one year or more from the issuance of the agency's initial decision is not unusual.

Figure 2



Source: American Health Planning Association, 2011

The National Institute for Health Care Reform published a research brief based on interviews with CON regulators in Connecticut, Georgia, Illinois, Michigan, South Carolina and Washington which shows stakeholder views vary widely about the effectiveness of CON regulations on access, quality and costs.[14] While respondents noted that CON regulations and their administration are not perfect, most expressed the opinion that CON programs should remain in place in their state and would benefit from increased funding for evaluation, improved compliance monitoring and movement toward a process driven more by data and planning rather than political influence.

Conclusions Regarding CON Regulation and Kentucky's CON Program

The consideration of the many aspects of CON regulation does not demonstrate that the process should be eliminated in Kentucky. CON deregulation could result in many unintended consequences that would be contrary to the statutory purpose of the CON program and to the goals of health care transformation and the Triple Aim. If CON regulations were to be reduced or eliminated, other policies would need to be in place to not only ensure quality of care, but provide additional financial support, such as through government subsidies and lower provider taxes, in recognition of the greater Medicaid and uncompensated care burden placed on Kentucky hospitals to maintain access to Medicaid, Medicare and low income patients.

There is no conclusive evidence that the elimination of CON regulation results in more cost effective services or improves access to needed care. The experience of other states that deregulation results in the fragmentation of services into smaller, specialty providers and the rapid proliferation of capital-intensive hospitals and ambulatory surgery centers. Kentucky has a network of viable, full-service hospitals throughout the state that will be challenged to continue vital services when the more profitable patients are diverted to boutique providers.

While one of CHFS' objectives in considering CON deregulation is to provide greater access, the result of such a change could have the opposite effect. The boutique providers and ASCs that will be developed will be focused on patients insured by commercial insurance companies. The loss of such patients will have a disproportionate financial impact on existing providers who will be left to serve a patient population from whom lower reimbursement is received. The financial impact from these new competitors could be the tipping point that would result in closure of some services or even entire rural or safety-net hospitals, thereby reducing geographic access for populations most in need. Any such reduction in access will only exacerbate existing challenges for rural and Medicaid patients and force these patients to travel longer distances for care.

The issue of enhancing access cannot be solved by simply adding more facilities. There are critical workforce shortages of health professionals to staff these facilities, and all of the available evidence suggests these shortages will only grow over time. Applying these resources effectively will be a critical consideration in the future and, without CON regulation, there will be no mechanism to ensure that the development of new facilities will not dilute the ability of existing providers to meet the needs of their patients.

[14] National Institute for Health Care Reform Research Brief, "Health Care Certificate-of-Need Laws: Policy or Politics?" Yee, T., Stark, L., Bond, A., and Carrier, E.; No. 4, May 2011.

Safety-net hospitals, those hospitals serving a high proportion of Medicaid and indigent patients, are particularly vulnerable to the effects of unfettered competition. A similar concern arises with respect to rural hospitals that are essential to ensuring access to emergency services and other primary and secondary health services. Rural hospitals and other safety-net hospitals together have the highest proportion of indigent care, as well as Medicaid patients. If new competitors are allowed entry without consideration of community needs, or their impact on these essential hospitals, as required to be demonstrated through the CON process, Kentucky will be faced with significant access problems for its most vulnerable populations.

Analysis of the Deloitte Report

In December 2013, the Deloitte consulting firm, under commission from CHFS, issued a report entitled: "The Commonwealth of Kentucky Health Care Facility Capacity Report." The stated purpose of this report:

> *"The objective of the facility capacity analysis was to test whether existing healthcare facility supply could sustain the increase in demand created as a result of anticipated insurance coverage changes across the Commonwealth. The Cabinet selected 18 distinct facility types that are subject to Certificate of Need (CON) and state licensure for further exploration."*[15]

Deloitte attempts to analyze the current capacity of these 18 facility/service types, develop projections of future demand considering the expansion in insurance coverage expected to occur under the Patient Protection and Affordable Care Act of 2010, and offer recommendations about the future CON regulation of each service. Deloitte also presents a discussion of CON regulation generally covering its history, the degree of CON regulation in states surrounding Kentucky, and the arguments for and against removing CON regulation in other states.[16]

A review of the recommendations in the Deloitte Report indicate the authors had an incomplete understanding of capacity requirements to accommodate future growth in demand and provided limited analysis of the impact of its recommended changes to the Kentucky CON program on the existing health care delivery system. A discussion of some of the key recommendations in the Deloitte Report is presented below.

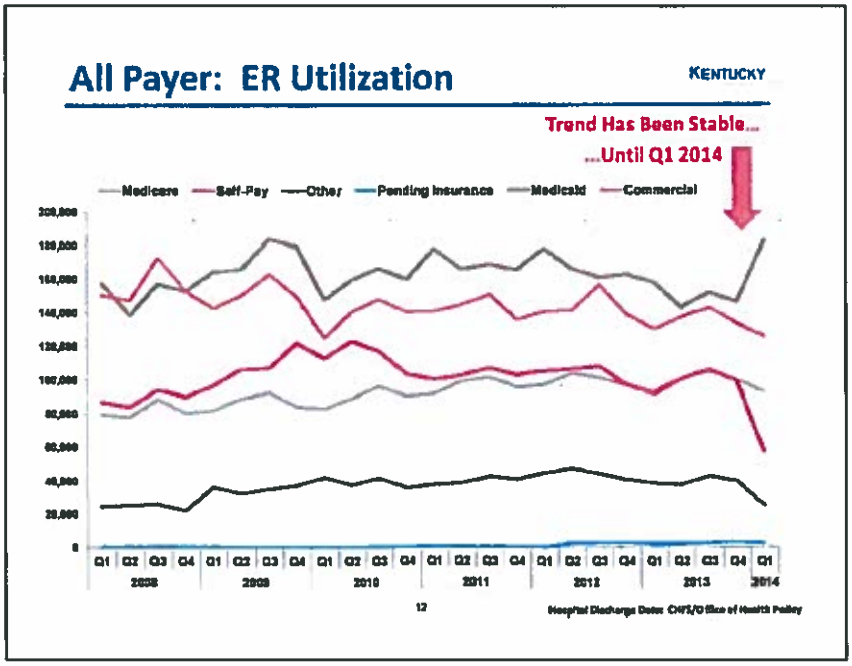
Future Growth in Demand

The key assumption in Deloitte's Report is that there will be an increase in demand, as a result of insurance coverage changes across the Commonwealth, which in turn will drive the need for capacity across a number of services. Kentucky hospitals report that overall volumes are not increasing substantially across most services, but rather they are seeing a direct proportionate change from self pay/charity to largely Medicaid coverage. Figure 3 is from a November 14, 2014 presentation by CHFS Secretary Haynes regarding the growth in Medicaid coverage. The significant majority of the individuals who have obtained coverage in Kentucky have been previously uninsured individuals who now qualify for Medicaid under Kentucky's expanded program. Hospitals in Kentucky have yet to see a surge in demand for services when comparing

[15] "The Commonwealth of Kentucky Health Care Facility Capacity Report." Deloitte, December 2013, p. 7.
[16] Deloitte, pp. 52-57.

data for the first six months of years 2013 and 2014. Despite the increase in the insured population, Kentucky hospitals have not seen an increase in utilization of services because patients must meet medical necessity criteria to be admitted to a hospital and because indigent patients were receiving care at Kentucky's hospitals before Medicaid expansion. Medicare, through its payment policies, has affected reductions in utilization of services, such as home health care, long-term acute care hospitals, and inpatient rehabilitation hospitals as well as shrinking the number of re-admissions to acute care hospitals from these settings. There are serious questions about the extent to which significant new health care facility capacity will be needed in the future and, as a consequence, the necessity of eliminating CON regulation to facilitate development of new capacity. The capacity that is needed to treat the newly insured under a "transformed" health delivery system includes greater access to primary care and primary care services are not generally regulated today under Kentucky's CON program.

Figure 3



Acute Care

Deloitte projects that demand for inpatient hospital services will decline in the future and noted that excess capacity exists in many of Kentucky's acute care hospitals. Specific recommendations included:

- *Manage capacity and scale through the following mechanisms:*
    - *Support consolidation of services into larger, regional facilities that can achieve economies of scale, particularly in metro areas and for high-acuity services (compare recent efforts of larger health systems to merge and rationalize regional services).*

- *Consider redistribution of licensed beds from low-performing to high-performing sites as measured by volume, quality, and patient satisfaction.*

- *Consider measures to reduce or repurpose overall acute care capacity across the Commonwealth*

- *Promote high-performing sites:*

  - *Encourage high performing sites by increasing financial incentives for quality and patient satisfaction above what is already included in ACA's pay-for-performance provisions.*

  - *Promote market self-regulation through increased transparency of quality and patient satisfaction data. A short-term measure may be to improve the user interface of the state's website that publishes hospital quality indicators (based on MONARHQ178). The objective is to offer patients clear and easy to access information and help consumers make an informed choice of provider.*

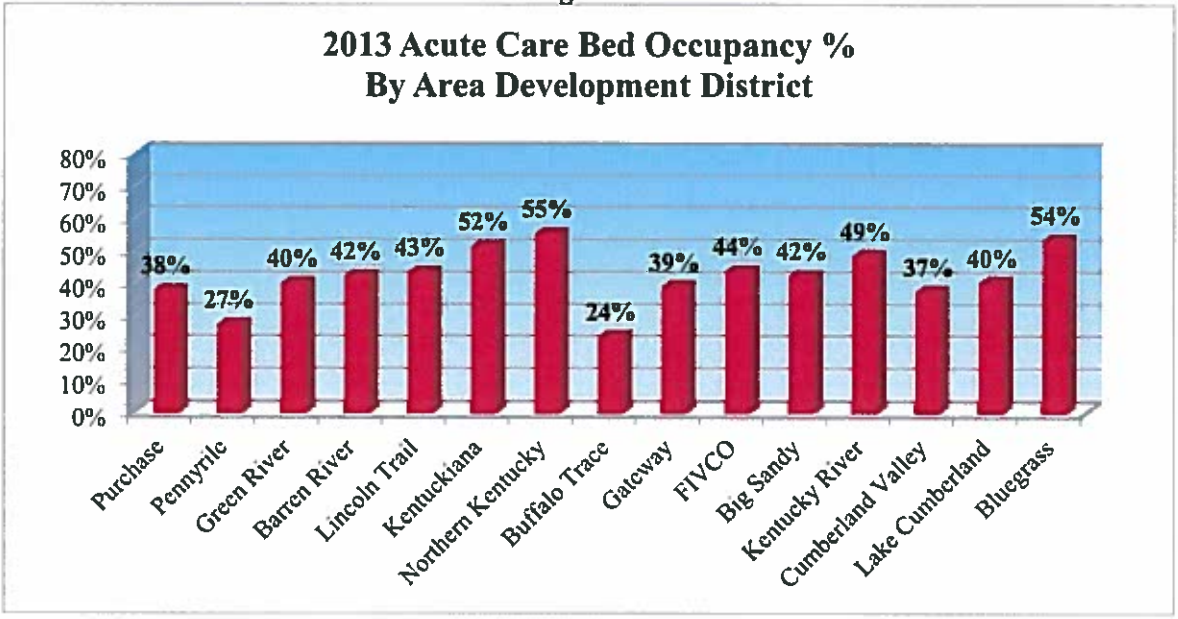
- *Reshape focus of Critical Access Hospitals (CAH)*

  - *Consider redesigning the types of services provided at Kentucky CAHs, increasing their role in delivering emergency and urgent care services while de-emphasizing non-urgent services.*

The recommendation to redistribute beds from "low-performing" sites to "high-performing" sites, while noble in its intent, poses significant real life problems in any effort to implement such a strategy. As a starting point, CHFS would have to be granted broad new statutory authority to compel hospitals to relinquish beds to another provider, which appears inconsistent with Deloitte's other recommendations that focus on reducing state regulation of health care facilities. Developing objective measures of quality and patient satisfaction to classify hospitals as low-performing or high-performing is equally problematic given the highly subjective nature of many of the measurement tools available today.

A second consideration is that hospital bed capacity is not a significant constraint on Kentucky hospitals today and is not likely to be in the future. Figure 4 presents the acute care hospital occupancy rates by Area Development District (ADD) in 2013. Notably, the issue of high performing hospitals being able to expand has already been addressed through the CON process as the State Health Plan recognizes that when functional capacity is reached, a facility may add additional beds.

Figure 4



The notion of providing financial incentives to hospitals for exceptional quality and patient satisfaction again is an attractive theoretical objective, but what mechanism does Kentucky have to implement such a program? Would the incentives be tied to Medicaid reimbursement, which now is operated through Medicaid Managed Care Organizations? Such Medicaid incentives are independent of any change in CON regulation, i.e., CHFS could adopt such policies with no changes to the CON program. Moreover, such policies will not address, and in fact may be antithetical, to ensuring access, which is a fundamental purpose of the CON program.

The recommendation to focus Critical Access Hospitals (CAHs) on emergency and urgent care services and de-emphasize non-urgent services appears too simplistic and not based on a detailed understanding of CAHs' individual circumstances. KHA has promoted the idea of allowing CAHs or other hospitals to emphasize emergency and ambulatory care (including ambulatory surgery services), with some specialized diagnostic equipment since there must be an opportunity for CAH's to obtain sufficient reimbursement from other outpatient services to support continuation of emergency services. This process exists already under the CON non-substantive review regulation and KHA has supported minor regulatory changes to that regulation to allow for a more seamless transition from acute/inpatient hospitals status to a comprehensive outpatient center. These regulations have been delayed thus far.

Elimination of CON regulation for ambulatory surgery and other outpatient diagnostic services would threaten the ability of CAHs and other vulnerable rural hospitals to survive under any delivery model if they faced competition from physician groups or outside investors for these profitable services. Any change affecting CAHs must be undertaken with extreme care given their importance in providing an accessible point of care for Kentucky's rural residents.

Home Health

Home Health Agencies provide critically important services for long-term care at home. The Report goes on to note that the need methodology in the Kentucky State Health Plan identified a need for additional home health agencies in several counties in Kentucky, but there have been few approvals of new home health agencies in recent years. With this background, Deloitte recommends:

> *Acknowledging the importance of home health services in providing community based care for the aging and disabled, the Commonwealth may consider avenues to promote availability and encourage standardization of services:*
>
> - *Encourage expansion of home health agencies into areas that have already been identified by the Cabinet as being underserved, or consider suspending/ discontinuing the CON program for Home Health Agencies.*

There are several problems with these recommendations. First, the Report assumes that the existing home health providers in Kentucky are incapable of addressing the growing need for home health care in the future. Home health agencies do not have a physical capacity as do hospitals and nursing homes. The ability of home health agencies to expand is primarily a function of having sufficient staff available to meet the demand for care. Approving more agencies has the effect of spreading relatively scarce staff resources, particularly in physical, occupational, and speech therapy, across more providers, thereby decreasing the efficiency of that staff.

A basic premise of Deloitte's recommendations is that the State Health Plan need methodology is a reasonable predictor of counties where patients are underserved with respect to home health services. The need methodology is based on comparing the actual utilization in each county to the projected utilization if the county were operating at the statewide average rate of home health patients served per capita. There are many reasons why a county may have a home health use rate below the Kentucky average including the relative health status of the population, the availability of alternatives to home health care in the community, and the practice patterns of physicians who must refer the patients for home health services. Many of the counties where a need is shown under the State Health Plan methodology already have numerous home health agencies.

Fayette County, for example, has the largest "un-served" need under the State Health Plan, but currently has 11 existing home health agencies and a wide range of other alternatives to home health care. An analysis of historical home health utilization data indicates that there is little correlation between the number of agencies serving a county and the rate of home health utilization in the county; therefore, approving more agencies for counties with numerous existing providers will likely to do little to change historical utilization patterns.

Deloitte acknowledged that, despite the fact that few new home health agencies have received CON approval in Kentucky in recent years, the rate of home health utilization has increased by 15% between 2006 and 2012. The limited number of CON approvals is a reflection of the fact that there are an abundance of existing providers with the ability to expand to meet patient

population needs and little evidence of patients requiring home health care who are not being served. Hearing Officers have carefully considered the need for each application without relying solely on the results of a simple numerical formula.

Simply eliminating CON requirements for the entry of new home health agencies will not benefit the residents of Kentucky. KHA previously recommended to CHFS that to meet the yet undetermined future need of the population for home health services licensed acute care hospitals should be permitted to establish or expand home health services, to their home county and contiguous counties they serves. This change will allow hospitals to better manage patients throughout the continuum of care and ensure that post-acute care services through home health are effective in the shared goal to reduce unnecessary hospital admissions. This would also support hospitals being able to better manage the cost of post-acute services under bundled payment, as well as to prevent unnecessary readmissions for which hospitals are penalized.

If expansion of home health services through hospital based agencies is deemed not sufficient to meet anticipated future need under new models of care, then KHA would support a second option for consideration to allow those existing Kentucky licensed home health agencies providing high quality home health services to expand to additional services areas or counties to meet potential growth in home health needs. The total elimination of CON regulations for home health services will not ensure that quality access will be enhanced and will result in greater competition for skilled staff, as well as reductions in volumes and financial performance for all agencies.

MRI and PET

Deloitte does project increases in demand for MRI and PET services in the future. Its recommendations regarding these services include:

- *Consider the appropriateness of CON regulation for MRI and evaluate whether the program should be discontinued because it has been effectively replaced by utilization management programs. Overall, new CON applications have been on the decline, while incumbents and physician-owned facilities can currently already expand.*

- *The Commonwealth may also consider de-regulating the PET market and instituting other demand management measures, such as pre-approvals and other care management methods.*

The decline in the number of CON applications for MRI services is largely due to the fact that ample MRI capacity exists across the Commonwealth in hospitals, freestanding centers, and physicians' offices. In 2012, there were 205 licensed and CON-exempt MRI units in Kentucky that performed a total of 423,116 procedures, according to the Annual MRI Utilization Report, which is an average of 2,063 procedures per unit, which is far below the capacity of such units.[17] After a long period of significant annual growth in MRI procedures, between 2011 and 2012 the number of MRI scans performed in licensed and CON-exempt facilities actually declined. The

[17] The State Health Plan sets a minimum utilization target of 2,500 procedures per MRI unit, but many units operated at substantially higher volumes.

removal of CON review for MRI services will have three possible results. There will be a further increase in the number of MRI units that will add to the excess capacity across Kentucky. Many MRIs could be developed with services offered and marketed on a cash basis to generate medically unnecessary services of questionable equipment quality and unknown provider expertise, yet this may not be apparent to consumers. Alternatively, CON-exempt units will apply for licensure and be eligible for higher reimbursement from Medicare and other payers with no change in services to the community.

Similar concerns exist with respect to deregulating PET services. The number of PET procedures performed in Kentucky has declined from 2009 to 2013. In 2013, 45 PET units across Kentucky performed 23,741 procedures, for an average of 522 procedures per unit, which is well below the 1,200 procedures per unit that the Kentucky State Health Plan standards require for new PET providers. There is no reason to encourage a proliferation of PET units when there is no capacity problem today or in the foreseeable future and further expansion will only serve to diminish the efficiency and quality of the existing programs.

Ambulatory Surgery Centers

The scope of regulation of ambulatory surgery centers (ASCs) has been the subject of debate in several states that maintain CON programs. The arguments for relaxed regulation of ASCs, often by physician groups, parallel the discussion in the Deloitte Report that ASCs provide a lower cost and more efficient setting for the provision of outpatient surgery and the movement of these surgeries out of the hospital setting is desirable under Health Care Reform. This assumption and other recommendations made by Deloitte are worthy of further analysis and discussion.

Deloitte made several observations regarding ambulatory surgery services in Kentucky that are incorrect. The first observation related to available capacity for ambulatory surgery:

> *Generally, the Commonwealth's occupancy for ambulatory surgery operating rooms is high across all MMCR's [Medicaid Managed Care Regions] relative to the minimum volume threshold set forth in the State Health Plan for ambulatory ORs in hospitals and freestanding ASC. Some MMCRs are experiencing occupancy rates double the threshold. A potential shortage in ambulatory surgery care is reflected in close to 20% of patients from MMCR's 4, 7, and 9 traveling outside of their region to receive ASC services. Projected 2017 utilization indicates that current capacity constraints will accentuate going forward for all MMCRs.*
>
> *The utilization analysis was based on major and minor ambulatory surgeries identified at the CPT code level as defined by Truven Outpatient Profiles. Surgeries do not include cystoscopy or other minimally-invasive procedures.*

It appears that Deloitte only looked at freestanding ASCs in its analysis despite the fact that the bulk of outpatient surgeries are performed in hospitals. In addition, Deloitte's analysis was based on a review of CPT data from Trueven, which requires considerable interpretation and does not indicate the setting in which a surgery was performed. More reliable sources of information on surgical volumes are the Cabinet's Annual Hospital Utilization and Services Report and the

Ambulatory Surgical Services Utilization Report, which are required to be used by CON applicants seeking expansion of ambulatory surgical services.

Figure 5 presents the utilization of freestanding ASCs in Kentucky under two different calculations: the standard hours per surgery and the hours per operating room set forth in the State Health plan and the actual surgical hours plus clean up time reported by each of these providers to the Cabinet. While some ASCs showed high utilization under the State Health Plan standards times, few of these facilities reached even 60% utilization using the actual surgical times that they reported. The explanation for this variance is that the State Health Plan uses time per outpatient surgery of 1.2 hours while the actual time per surgery at these facilities was considerably shorter. The State Health Plan sets a target utilization rate of 85%, and none of the ASCs approached that utilization level in 2013. Contrary to Deloitte's conclusions, there is significant unused operating room capacity in Kentucky's freestanding ASCs, which will be able to accommodate future growth in demand for such services.

Figure 5
Kentucky Freestanding Ambulatory Surgery Centers
2013 Utilization

Facility	County	% SHP Calculated Used Capacity	% Used Capacity by Reported Hours
Bluegrass Surgery & Laser Center	Jefferson	133.6%	51.3%
Cumberland Valley Surgical Center	Laurel	332.6%	34.6%
Commonwealth Eye Surgery Center	Fayette	101.4%	46.1%
McPeak Surgery Center	Barren	93.4%	22.9%
Lexington Clinic	Fayette	76.9%	68.0%
Surgecenter of Louisville	Jefferson	73.3%	26.4%
The Eye & Laser Surgery Center Of Paducah	McCracken	71.0%	35.3%
Gastrointestinal Endoscopy Ctr of Owensboro	Daviess	70.7%	60.4%
Louisville Surgery Center	Jefferson	67.5%	63.9%
Central Kentucky Surgery Center	Boyle	60.9%	77.9%
Kentucky Surgery Center	Fayette	62.6%	45.2%
Dupont Surgery Center	Jefferson	53.8%	29.5%
Lake Cumberland Surgery Center	Pulaski	40.5%	29.8%
The Center for Surgical Care	Boone	37.7%	31.3%
Owensboro Surgery Center	Daviess	40.9%	22.2%
Endoscopy and Surgical Center of Lexington Clinic	Fayette	29.3%	34.1%
Lexington Surgery Center	Fayette	25.1%	25.2%
Muhlenberg Surgery Center	Muhlenberg	38.6%	24.6%
Bluegrass Orthopaedics Surgical Division	Fayette	22.0%	25.8%

Ambulatory Surgery Center	McCracken	149.0%	33.1%
Somerset Surgery Center	Pulaski	17.5%	69.5%
Dermatology Associates of Kentucky	Fayette	16.8%	23.7%
Premier Surgery Center of Louisville	Jefferson	30.3%	18.6%
Eyecare Network	Mason	9.6%	5.6%
Louisville Endoscopy Center	Jefferson	0.0%	0.0%
Stone Road Surgery Center	Fayette	75.9%	33.5%
Tri State Digestive Disorder Ctr	Kenton	0.0%	0.0%
Source: 2013 Ambulatory Surgical Services Utilization Report			

The utilization of these freestanding ASCs was summarized by Medicare Managed Care Region, as presented in Figure 6. While the reported utilization was high in MMCR 8, which includes a single facility, all of the regions had significant excess capacity based on the standards in the State Health Plan.

Figure 6
2013 Utilization of Freestanding Ambulatory Surgery Centers
By Medicaid Managed Care Region

Medicaid Managed Care Region	% SHP Calculated Used Capacity	% Used Capacity by Reported Hours
MMCR 1	39.2%	34.0%
MMCR 2	39.1%	30.3%
MMCR 3	60.3%	32.8%
MMCR 4	41.9%	44.3%
MMCR 5	42.2%	40.2%
MMCR 6	37.7%	31.3%
MMCR 7	9.6%	5.6%
MMCR 8	332.6%	34.6%

To have a complete picture of the availability of surgical capacity to perform outpatient surgeries, it is necessary to include hospital providers as well. Figure 7 presents the average utilization rate of operating rooms, including hospitals, hospital-based ASCs, and freestanding ASCs, by ADD. While the Deloitte Report evaluated utilization by MMCR, ADDs are the traditional health planning areas; and with 15 ADDs, versus 8 MMCRs, the ADD analysis provides a more detailed picture of surgical capacity. As these data indicate, there is massive unused operating capacity across Kentucky whether calculating utilization based on the State Health Plan criteria or using actual surgical times reported by individual providers. Permitting

the unregulated development of new freestanding ASCs will only exacerbate the degree of surplus capacity.

Figure 7

2013 Total Operating Room Utilization By ADD

ADD	% SHP Calculated Used Capacity	% Used Capacity by Reported Hours
Purchase	37%	50%
Pennyrile	28%	48%
Green River	38%	46%
Barren River	42%	56%
Lincoln Trail	50%	40%
Kentuckiana	43%	62%
Northern Kentucky	34%	43%
Buffalo Trace	33%	40%
Gateway	41%	48%
FIVCO	64%	81%
Big Sandy	52%	63%
Kentucky River	33%	65%
Cumberland Valley	49%	52%
Lake Cumberland	34%	54%
Bluegrass	40%	59%

Source: 2013 Kentucky Annual Ambulatory Surgical Services Report and Annual Hospital Utilization and Services Report

The claims that ASCs offer lower costs than hospital-based surgical services is based primarily on a comparison of the prices charged in each setting. Hospitals necessarily have higher costs because of the broad mission they serve and surgical services help support the many other unprofitable services they offer. Medicare reimburses hospital-based outpatient surgery at a somewhat higher rate than freestanding ASCs in recognition of the fact that hospitals' cost structures are higher because of the essential services they must support. If those outpatient surgeries are shifted from hospitals to freestanding ASCs, the hospital's infrastructure costs do not go away.

Physicians already have the ability to perform ambulatory surgeries in their offices without CON review. Some physician groups are seeking the elimination of CON requirements for the primary purpose of being able to collect facility fee reimbursement from Medicare and other payers, which they are currently not eligible to receive as unlicensed, office-based surgery centers. Increasing reimbursement to these surgery centers will do nothing to enhance access to services and will simply increase overall health care spending.

Deloitte noted that patients were leaving one MMCR to receive ambulatory surgery in another MMCR, implying that these patient migration patterns were a function of inadequate outpatient surgery capacity in some regions. There is no factual basis for this assertion. In fact, patients travel from one area of Kentucky to other areas for a range of reasons, none of which are tied to capacity. In some cases, certain specialists do not practice in a community and patients must travel to a larger community to seek care. Physician referral patterns also determine where patients seek care. Patient preference also plays a role with patients sometimes seeking to go to large tertiary centers for treatment even when services are available locally.

Deloitte also asserted that all 43 ASC applications submitted since January 1, 2003 were denied. This statement is incomplete because during that same period, 23 CON applications for ASCs were approved under nonsubstantive review.

Allowing further expansion of freestanding ASCs in Kentucky does not mean that all patients will have greater access to care. The Medicare Payment Advisory Commission[18] recently found:

> *There is evidence that patients treated in ambulatory surgical centers (ASCs) are different in several ways from those treated in hospital outpatient departments (HOPDs). Our analysis of Medicare claims from 2012 found that the following groups are less likely to receive care in ASCs than in HOPDs: Medicare beneficiaries who also have Medicaid coverage (dual eligibles), African Americans (who are more likely to be dually eligible), beneficiaries who are eligible for Medicare because of disability (under age 65), and beneficiaries who are ages 85 or older...In a separate analysis, we found that patients treated in HOPDs in 2010 were, on average, more medically complex than patients treated in ASCs, as measured by differences in average patient risk scores.*

The implications of these findings are important to evaluating the impact of a significant increase in the number of ASCs in Kentucky. The ASCs are more likely to serve the healthiest, insured patients while hospitals will serve a higher proportion of medically complex and Medicaid patients who require a higher intensity of resources for lower payment.

The vast majority of freestanding ASCs are owned by physicians or physicians in conjunction with outside developers. A study of ASCs in Florida considered the question of physician-owned ASCs and the overutilization of such services.[19] The authors found increased surgery use subsequent to a physician's acquisition of ownership status in a surgicenter. Another study examined orthopedic surgeons' ownership of ASCs and specialty hospitals in Idaho, a state without CON regulation. [20] This study also found higher use rates by physician owners, which "suggests that financial incentives linked to ownership of either specialty hospitals or ambulatory surgery centers influence physicians' practice patterns."

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[18]MedPAC, "Report to Congress : Medicare Payment Policy," March 2014, 125-126.

[19] By Hollingsworth, J. et al., "Physician-Ownership Of Ambulatory Surgery Centers Linked To Higher Volume Of Surgeries," *Health Affairs*, April 29, 2010, 683-689.

[20] Mitchell, J., "Effect of Physician Ownership of Specialty Hospitals and Ambulatory Surgery Centers on Frequency of Use of Outpatient Orthopedic Surgery," *Arch Surg.*, 2010;145(8):732-738

Deloitte made the following recommendations regarding ASCs:

> *Temporarily cease CON process for ASCs in order to allow more freestanding ASCs to come online. This will increase market competition and provide consumers with viable alternatives to hospital-based care.*
>
> - *Consider relaxing the proximity requirement stipulating 20-minute drive time to closest backup acute care hospital. The proximity requirement may not be medically warranted for smaller ambulatory surgery procedures. In comparison, for cardiac cath, the State Health Plan does not set a proximity requirement but requires a 24x7 consultation service.*
>
> - *Use reimbursement for ambulatory surgeries as economic lever to further encourage conducting surgical procedures in an outpatient setting rather than by admitting patients to hospitals.*

The idea of "temporarily" ceasing CON for ASCs is extremely problematic. The likelihood is that with the elimination of CON requirements there would be a surge of new ASC development across Kentucky with all of the potential impacts described above. Would it then make sense to reestablish ASC regulation after the disruption from the period of deregulation was already felt?

The 20-minute drive time standard in the State Health Plan was adopted to ensure that patients would have ready access to emergency hospital treatment in the event of an adverse outcome. While the need to access hospital emergency services may not occur frequently for "smaller ambulatory surgery procedures," adverse events are not possible to predict, as the recent event with comedian Joan Rivers demonstrates. More importantly, many procedures performed in ASCs are not "small" and there would be no limit on the type of procedures that could be performed in ASCs located distantly from hospitals if CON regulations were removed.

The final recommendation to use reimbursement as an economic level to move surgical procedures from hospitals to ASCs is flawed in several respects. First, few patients are "admitted to hospitals" as inpatients who could safely receive surgery on an outpatient basis. In 2013, 69% of all surgeries performed in hospitals were done on an outpatient basis. Kentucky has limited ability to implement the financial incentives that Deloitte recommends because Medicare and other payers cover the significant majority of Kentucky residents. A policy to encourage redirection of patients from hospital outpatient surgical facilities to freestanding ASCs would also have profound negative financial consequences for Kentucky's hospitals as well as increasing the risk of patients receiving outpatient surgery at a facility not capable of providing an adequate emergency response when complications are encountered.

Given the lack of need for additional surgical capacity in Kentucky, these Deloitte recommendations would not lead to desirable health planning outcomes. Furthermore, the Kentucky General Assembly has twice weighed in on the issue of ASCs. Legislation was passed in 2012 clarifying legislative intent by specifically mandating that ASCs be required to obtain a CON. Then, in the 2014 legislative session, the Kentucky General Assembly took action to assure that CON review for ASCs would be conducted under the formal review process by requiring that the State Health Plan contain specific review criteria that is based on population

need. In taking these actions, the General Assembly recognized the importance of CON in assuring quality and access as it relates to outpatient surgery. In summary, the CON-related recommendations in the Deloitte Report should not be accepted by CHFS. If implemented, they would result in the creation of significant unneeded new service capacity that would be disruptive to existing Kentucky providers which could in turn reduce access to care and patient safety if existing hospitals providing high quality emergency care are financially compromised. Such action would also contravene the intent of the legislature which has shown ongoing support for maintaining CON for ASCs.

Special Needs of Rural Communities

Nearly half of Kentuckians (45%) live in a rural area and are served by Kentucky's 65 rural, acute care hospitals. Twenty-eight of these hospitals are designated as critical access hospitals (CAH), a special designation by the Centers for Medicare and Medicaid Services (CMS) for small and rural hospitals with a limited number of beds. These CAHs are essential to their local communities.

Rural hospitals operate as health care "hubs" for rural Kentuckians, providing 24/7 emergency care, comprehensive diagnostics, primary care clinics, access to specialty care and long term treatment of chronic diseases. Of equal importance, rural hospitals are the primary recruiters of physicians to smaller communities. Without rural hospitals, physician coverage in many of these areas would be severely reduced as would the availability of outpatient clinics and, in some cases, ambulance services. Rural hospitals are also one of the strongest economic engines in their communities, providing a stable workforce and good wages.

Rural hospitals already face significant financial challenges. Government payers (Medicare and Medicaid) account for 77% of patient volumes, yet payments from Medicare and Medicaid fall short of covering the cost of care.

- Medicare reimbursement to hospitals averages 92% of cost
- Medicaid reimbursement to hospitals averages 85% of cost
- Critical access hospitals only receive about 99% of cost due to federal sequestration

Rural hospitals have very little commercial reimbursement in comparison to government payers and charity care to offset the substantial revenue losses. The elimination of CON regulation could shrink the base of commercial payers even further because such patients would be the target of newly developed facilities in an unregulated market.

Rural hospitals are an efficient vehicle for providing care. These facilities consume fewer Medicare resources per capita than urban facilities. A study by Ivantage reports that Medicare payments to rural beneficiaries are a mere 22.5 percent of total hospital payments. In fact, in 2010, the average cost per rural beneficiary was 3.7 percent lower than the average cost per urban beneficiary for comparable service adjusted by case mix.

Again, the most likely services to be developed in rural areas with a change in CON regulations would be ASCs and outpatient diagnostic services such as MRI. These services typically provide

positive operating margins for rural hospitals and the loss of such services could destabilize the financial viability of these small hospitals. As discussed above, the closure of such hospitals or the necessity of reducing their scope of services would result in residents of these areas having to travel longer distances to receive care, and it would result in the loss of health care jobs important to the local economy served by these facilities.

Conclusions

Significant changes to Kentucky's CON program are unlikely to facilitate the achievement of CHFS' core objectives. New health delivery systems will be driven by new payment models, which are already being implemented through Medicare payment reform, rather than the elimination of CON regulations. In fact, the reduction or elimination of CON regulations in Kentucky could frustrate efforts of Kentucky providers to adopt new models of care delivery because markets will be more fragmented and financial resources will more be limited. The Kentucky CON program will provide stability and predictability during the difficult transition period to value-based care delivery.

Kentucky's CON program, as currently constituted, is not onerous and allows considerable flexibility to providers to undertake needed projects. Certain expenditures are exempt from review and many other projects qualify for an expedited nonsubstantive review process. Kentucky's CON process is also considerably less burdensome than those of other states' CON programs.

The Deloitte Report, which CHFS commissioned to examine the needs of a changing a delivery system, suffers from a number of deficiencies in its assumptions, analyses, and conclusions. There is ample capacity in Kentucky's existing health care system to accommodate much of the future growth that may or may not arise from an expanded pool of insured individuals. CFHS should reject Deloitte's specific recommendations regarding CON deregulation.

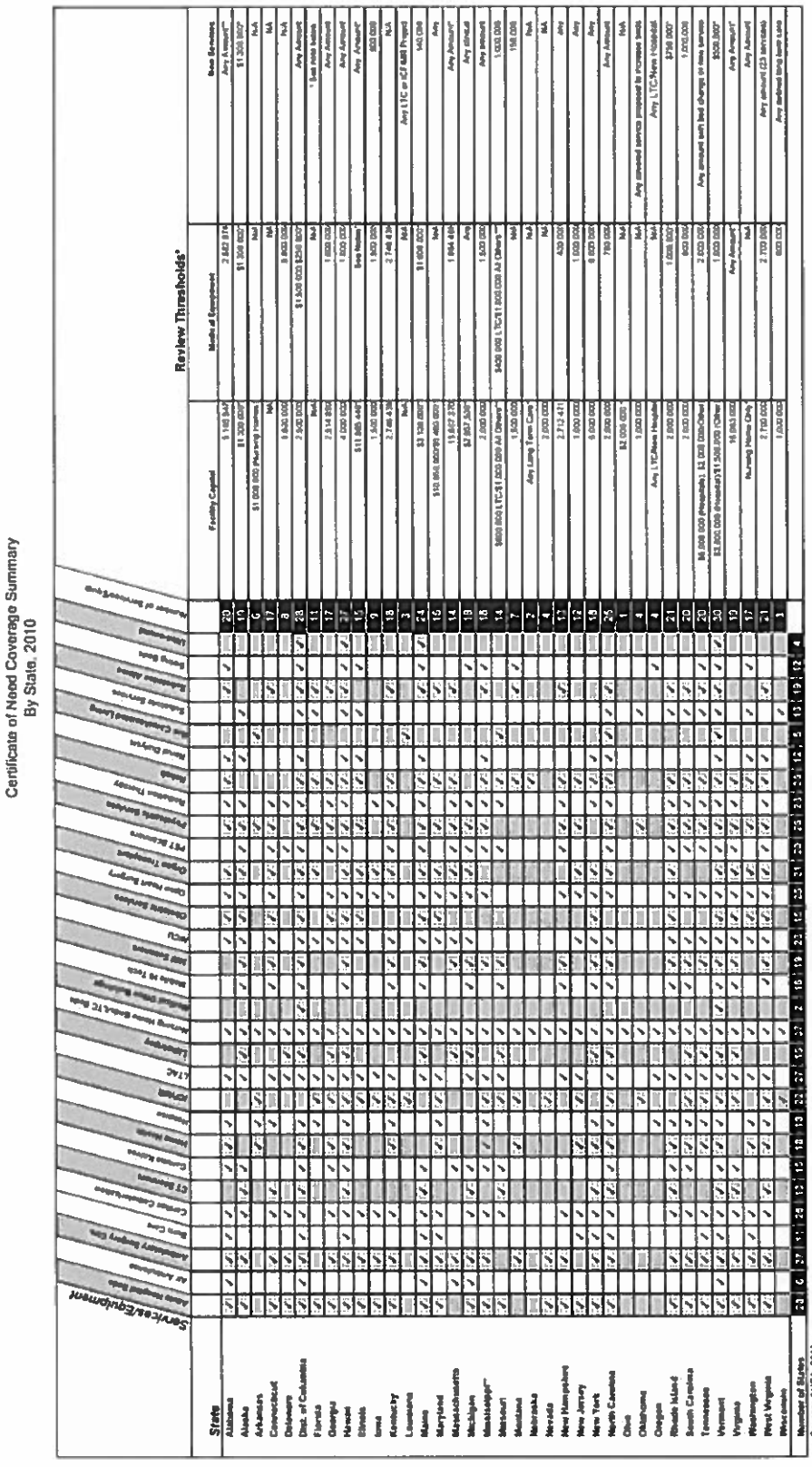
Lessons from other states that have deregulated should be a cautionary tale to Kentucky. The elimination of CON review will create significant short-term disruptions with no long-term payback. Changes in CON regulations regarding ASCs, in particular, will have significant negative impacts. The network of rural hospitals and safety-net hospitals that ensure essential health care access across the Commonwealth are the most vulnerable to the market disruptions that CON deregulation would create.

KHA does oppose significant changes to CON regulations which would be contrary to the statutory goal of the program and would result in substantial proliferation of unneeded health services. As noted above, KHA supports changes to home health standards that recognize the needs of new delivery models to provide a comprehensive continuum of care. KHA also supports a change that would allow hospitals seeking to convert to a different model of offering only emergency and outpatient services to do so through nonsubstantive review.

The evolution of health care delivery in Kentucky, whatever final form it takes, is dependent on a stable health care market through continuation of the CON program. Selected modifications to regulations responding to changing conditions have and should continue to be part of Kentucky's CON program. CHFS should consider changes in CON regulations to accommodate the special

needs of new delivery models and other components of a population health system in the future that is based on the needs of communities, rather than adopt a free-market approach that will not ensure uniform access to care for all citizens of the Commonwealth.

Appendix A.


Certificate of Need Coverage Summary
By State, 2010
Review Thresholds*

COMMONWEALTH OF KENTUCKY
CONTRACTOR TIME REPORTING

PAY PERIOD ENDING: 11/30/2014
Printed on: 12/8/2014

NAME: ANDREA ADAMS
VENDOR: NTT DATA

TASK ORDER #: 1300923
TASK END DATE: 06/30/2015
AVAILABLE HOURS: 1288

	Regular hours	Leave w/o pay
11/16/2014		
11/17/2014	8.00	
11/18/2014	8.00	
11/19/2014	8.00	
11/20/2014	8.00	
11/21/2014	8.00	
11/22/2014		
11/23/2014		
11/24/2014	8.00	
11/25/2014	8.00	
11/26/2014	8.00	
11/27/2014		
11/28/2014		
11/29/2014		
11/30/2014		
Totals	**64.00**	**0.00**

I certify that the daily hours worked are correct.

Contractor's Signature

Supervisor's Signature